

ALLEGED VIOLATION: On or about October 10, 11, 12, and 15, 1951, while a number of *methyltestosterone tablets*, *thyroid tablets*, *dextro-amphetamine sulfate tablets*, *methamphetamine hydrochloride tablets*, and *tablets containing a mixture of phenobarbital and mannitol hexanitrate* were being held for sale at the Reavis Drug Co., after shipment in interstate commerce, one bottle of *thyroid tablets* was caused to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician, and various quantities of the other drugs were caused to be repacked and dispensed without prescriptions, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *thyroid tablets* failed to bear adequate directions for use. (The bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempt from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of causing the dispensing of the drug without a physician's prescription caused the exemption to expire.)

Further misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), portions of the repackaged *methyltestosterone tablets* and *dextro-amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *tablets containing a mixture of phenobarbital and mannitol hexanitrate* contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 22, 1952. The defendant having entered a plea of nolo contendere, the court fined him \$350.

4023. Misbranding of sulfadiazine tablets, thyroid tablets, and methamphetamine hydrochloride tablets. U. S. v. Alvin H. Weinstein. Plea of nolo contendere. Fine, \$75. (F. D. C. No. 34360. Sample Nos. 12081-L, 12726-L, 12729-L.)

INFORMATION FILED: April 23, 1953, Northern District of Ohio, against Alvin H. Weinstein, acting manager for the Schwartz Drug Co., Toledo, Ohio.

ALLEGED VIOLATION: On or about March 13 and 18, 1952, while a number of *sulfadiazine tablets*, *thyroid tablets*, and *methamphetamine hydrochloride tablets* were being held for sale at the Schwartz Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to

be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug.

Further misbranding, Section 502 (f) (2), the repackaged *sulfadiazine tablets* and *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 23, 1953. The defendant having entered a plea of nolo contendere, the court fined him \$75.

4024. Misbranding of dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, and capsules containing a mixture of Seconal Sodium and Amytal Sodium. U. S. v. Marshall W. Walton (Walton's Drug Store). Plea of guilty. Fine, \$150. (F. D. C. No. 34349. Sample Nos. 31019-L, 34330-L, 34373-L, 34483-L, 34484-L, 34488-L.)

INFORMATION FILED: February 21, 1953, Western District of Missouri, against Marshall W. Walton, trading as Walton's Drug Store, Springfield, Mo.

ALLEGED VIOLATION: On or about March 17, 18, and 27, 1952, while a number of *dextro-amphetamine sulfate tablets*, *amphetamine sulfate tablets*, and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were being held for sale at Walton's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *capsules containing a mixture of Seconal Sodium and Amytal Sodium* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* failed to bear labels containing the common or usual name of each active ingredient of the drugs.

DISPOSITION: March 4, 1953. The defendant having entered a plea of guilty, the court fined him \$150.